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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,660	09/15/2005	Jean-Louis Junien	102717.58257US	9879

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EXAMINER	
ZHANG, NANCY L	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/18/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,660	JUNIEN ET AL.	
	Examiner	Art Unit	
	Nancy L. Zhang	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 11-17 are pending and examined.

Claim Objections

Claim 12 is objected to because of the following informalities: it is not an appropriate recitation of a Markush Group. The components in a Markush group should be linked by commas and the conjunction of "and" should be used to link the last two components of the Markush group.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 11, the phrase "an effective dosage of a PPARα agonist" renders the claim indefinite because the claim includes elements not actually disclosed which could mean the dosage of a PPARα agonist being effective for anything, thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d). The "treating obesity" in the preamble of claim 11 may be implied as being what is meant for

"an effective dosage of a PPARα agonist" but this is implied at best. An implied limitation is not clear and concise as required under 112, second paragraph.

Claim 15 recites the limitation "the effective dosage of metformin" in claim 11. There is insufficient antecedent basis for this limitation in the claim.

Lack Written Description Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 12-13 are directed to a method of treating obesity by co-administering a PPARα agonist and metformin where the PPARα agonist is a fibrate including a fibric acid derivative or an ester of fibric acid derivative without any structural limitation. The specification only provides some example fibrate compounds such as gemfibrozil, fenofibrate, bezafibrate, clofibrate and ciprofibrate being PPARα agonists but does not provide any structural limitation that supports the compounds of fibric acid derivatives or esters of fibric acid derivatives. The disclosure does not meet the written description provision of 35 USC § 112, 1st Paragraph. The specification provides insufficient

written description to support the genus of fibric acid derivatives or esters of fibric acid derivatives encompassed by claims 12-13.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is not claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skilled in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

In the instant case, a skilled artisan cannot envision the detailed chemical structure of fibric acid derivatives or esters of fibric acid derivatives. Adequate written description requires more than a mere statement that it is part of the invention and reference to potential compounds. The chemical itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F. 2d 1008, 1012, 10 USPQ2D 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by

describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2D at 1966.

Therefore, claims 12-13 do not meet the written description provision of 35 USC § 112, 1st Paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11, 14 and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. (US PGPub 2002/0173663, filing date: Aug. 17, 2001).

Claims 11, 14 and 16-17 are directed to a method of treating obesity comprising co-administering an effective dosage of a PPARα agonist and metformin. Claims 14 recites the limitation that the dosage of PPARα agonist is about 10 to 3000 mg per day. Claim 16 recites the limitation that PPARα agonist and metformin are administered simultaneously. Claim 17 recites the limitation that PPARα agonist and metformin are administered sequentially.

Liu et al. teach a method of treating obesity (page 24, left column, claim 25, line 6) comprising the administration of an effective amount of a compound of Formula (I) (see page 24, right column, lines 10-11) which is a potent PPARα agonist (see page 6, paragraph [0079], lines 1-3) and an effective amount of one or more other drugs (see page 24, right column, lines 12-13) such as metformin (see page 24, right column, lines 18-19). Therefore, Liu et al. disclose a combination of a PPARα agonist - compound of Formula (I) and metformin. Liu et al. further disclose that the PPARα agonist compound of formula (I) is administered at a total daily dosage from about 1.0 mg to about 1000 mg (page 6, paragraph [0084], lines 9-10). Furthermore, Liu et al. disclose that the compound of formula (I) and other drugs may be administered contemporaneously (same meaning as simultaneously) or sequentially (page 7, paragraph [0093], lines 5-7).

Therefore, a method of treating obesity by co-administering a PPARα agonist and metformin as claimed in claims 11, 14 and 16-17 is clearly anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al. (US Patent 5,190,970, issue date: Mar. 2, 1993) in view of Beisswenger et al. (US PGPub. 2001/0031790, pub date: Oct. 18, 2001) and Rink et al. (US Patent 5,739,106, issue date: Apr. 14, 1998).

The invention of claims 11-17 is directed to a method of treating obesity comprising co-administering an effective dosage of a PPARα agonist and metformin. Further limitations include specific PPARα agonists such as fenofibrate (claims 12-13);

daily dosage of the PPARα agonist (claim 14); daily dosage of metformin (claim 15) and the manner of which the two drugs are administered (claims 16-17).

Pan et al. disclose fenofibrate tablets containing 250 mg fenofibrate for treating type II diabetes (column 14, example 7) and the dosage forms can be administered to the patient one to four times per day (column 12, lines 28-29).

The difference between Pan et al.'s disclosure and the instant claim lies in that the prior art fails to teach (i) the combination of fenofibrate and metformin for the treatment and (ii) the treatment for obesity.

However, Beisswenger et al. disclose metformin for treating type 2 diabetes using dosage of 1000 mg per day (page 2, paragraph [0014], lines 1-8).

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior." Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to co-administer fenofibrate and metformin in a combined therapy for treating type II diabetes, motivated by their having been taught by the prior art to be useful in treating type II diabetes, consonant with the reasoning of the cited case law.

With respect to treating obesity, Rink et al. disclose that obesity and type 2 diabetes are associated in both clinical and epidemiological studies (column 1, lines 29-31) and that weight reduction is often recommended as the first course of action for

patients suffering from Type II diabetes (column 1, lines 42-45). Therefore, one having ordinary skill in the art would have been motivated at the time of the instant invention to practice the combined therapy of treating type II diabetes to treat obesity by co-administer fenofibrate and metformin to result in the practice of the instant invention with a reasonable expectation of success.

Regarding claims 16-17, the determination of the order of which the two active ingredients of a combined therapy is routinely made by those of ordinary skill in the art and is well within the ability of tasks routinely performed by them without undue experimentation. Thus, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to administer fenofibrate and metformin simultaneously or sequentially with a reasonable expectation of success.

Regarding the recitation of PPARα agonist, since the PPARα agonist fenofibrate is identical to the prior art compound fenofibrate, the recitation of PPARα agonist is merely a characteristic of the compound fenofibrate.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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NLZ

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PRIMARY EXAMINER